REMARKS

Claims 1-29 were considered in the non-final Office action mailed on January 5, 2007. As reflected in the listing of claims beginning on page 2 of this paper, Applicants amend claims 1, 6, 12, 14, 19, 24, 25, 27, 28 and 29, cancel claims 13 and 26 and introduce new claim 30 herein. Support for the amendments and new claim can be found throughout the specification, claims and figures as originally filed, including, for example, at paragraphs [0026], [0029], [0030], [0044] and [0046] and Figures 5-7 and 8A-8C. Applicants submit that no new matter is introduced by the amendments and new claim. Following entry of the amendments, claims 1-3, 5-12, 14-16, 18-25 and 27-30 will be pending for the Examiner's consideration.

Explanation of Applicant's Invention

Applicants' front-end loader 12 forms part of a percutaneous transluminal system 10 for delivering or retreiving an intracardiac device, for example, a prosthetic occluder 200, to or from an anatomical site in a patient. The prosthetic occluder 200 occludes an anatomical defect, such as an intracardiac defect, at an anatomical site in a patient. The front-end loader 12 comprises a proximal portion 21. The proximal portion 21 comprises a proximal end 20, a distal end 19 and an expanded lumen 26 positioned between the proximal end 20 and distal end 19. The expanded lumen 26 tapers towards the distal end 19 of the proximal portion 21. The front-end loader 12 further comprises a distal portion 27. The distal portion 27 comprises a tube 15 having a proximal end 24, a distal end 17 and a lumen 18 extending through the proximal end 24 and distal end 17 of the tube 15. Carpenter, paragraphs [0031], [0035] and Figure 2.

The distal portion 27 of Applicants' front-end loader 12 has a beveled end 22 positioned at the distal end 17 of the tube 15 to receive the intracardiac device, for example, a prosthetic occluder 200, into the lumen 18 of the distal portion 27 of the front-end loader 12 for percutaneous transluminal delivery or retreival of the prosthetic occluder 200 to or from the anatomical site in the patient. The distal portion 27 can also have a chamfered rim 25 positioned at the distal end 17 of the tube 15 to receive the prosthetic occluder 200 into the lumen 18 of the distal portion 27. The chamfered rim 25 has an outer rim 70 and an inner rim 72, the inner rim 72 positioned proximal to the outer rim 70. Carpenter, paragraphs [0039], [0040], [0041] and Figure 2.

Applicants' front-end loader 12 can be used to deliver or to retrieve a collapsible intracardiac device, for example, a prosthetic occluder 200, to a patient to occlude an anatomical defect at an anatomical site in a patient. According to Applicants' delivery method, the prosthetic occluder 200 is received in the lumen 18 of the tube 15 of the front-end loader 12, the prosthetic occluder 200 is delivered to the patient and the prosthetic occluder 200 is implanted at the anatomical site in the patient. According to the retrieval method, the prosthetic occluder 200 is received into the lumen 18 of the tube 15 of the front-end loader 12 and the prosthetic occluder 200 is retrieved from the patient. Carpenter, [0046]-[0050], Figures 5-7 and 8A-8C.

Rejections under 35 U.S.C. § 102(b)

Claims 1, 4, 5, 11-13, 14, 17, 18 and 24-27 were rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Patent No. 6,592,546 to Barbut et al. ("Barbut"). Applicants traverse the rejections to the extent the rejections are maintained over the amended claims.

Amended independent claim 1, upon which claims 4, 5 and 11-13 depend, recites a front-end loader for a percutaneous transluminal system for an intracardiac device. Applicants' claimed front-end loader comprises a proximal portion comprising a proximal end, a distal end and an expanded lumen positioned therebetween, the expanded lumen tapering towards the distal end of the proximal portion. Applicants' claimed front-end loader further comprises a distal portion comprising a tube comprising a proximal end, a distal end, a lumen extending therethrough, and a beveled end. Applicants' claimed beveled end is positioned at the distal end of the tube and the beveled end receives the intracardiac device into the lumen of the distal portion of the front-end loader.

Amended independent claim 14, upon which claims 17, 18 and 24-26 depend, recites a front-end loader for a percutaneous transluminal system for an intracardiac device. Applicants' claimed front-end loader comprises a proximal portion comprising a proximal end, a distal end and an expanded lumen positioned therebetween, the expanded lumen tapering towards the distal end of the proximal portion. Applicants' claimed front-end loader further comprises a distal portion comprising a tube comprising a proximal end, a distal end, a lumen extending therethrough, and a chamfered rim. Applicants' claimed chamfered rim is positioned at the distal end of the tube and comprises an outer rim and an inner rim, the inner rim positioned proximal to

the outer rim. The distal end of Applicants' claimed tube receives the intracardiac device into the lumen of the distal portion of the front-end loader.

Amended independent claim 27 recites a method for delivering a collapsible intracardiac device to a defect at an anatomical site in a patient. Applicants' claimed method comprises providing a front-end loader comprising a proximal portion comprising an expanded lumen and a distal portion comprising a tube comprising a proximal end, a distal end, a lumen extending therethrough, and a beveled end, the beveled end positioned at the distal end of the tube. Applicants' claimed method further comprises receiving the intracardiac device in the lumen of the tube, delivering the intracardiac device to the patient and implanting the intracardiac device at the anatomical site in the patient.

Applicants submit that claims 1, 14 and 27 are patentable over Barbut at least because Barbut does not teach or suggest receiving an intracardiac device into the lumen of the distal end of a tube as required by claims 1, 14 and 27. Instead, Barbut teaches that both its filter 75 and its balloon occluder 65 are fixed to the outer diameter and around the circumference of Barbut's cannula 10. Barbut, col. 17, lines 1-4; col. 18, lines 32-41; col. 28, lines 30-34 and Figures 1, 2A-2C, 22 and 23. Barbut, in contrast to Applicants' claimed invention, also teaches that its filter 75 and balloon occluder 65 are introduced and removed from the patient in a deflated, fully contracted condition about Barbut's cannula. Barbut, col. 19, lines 49-51 and col. 20, lines 12-25. Accordingly, neither Barbut's filter nor Barbut's balloon occluder are capable of being received into the lumen of a tube.

Further, Barbut teaches that its filter mesh 75 is bonded at its distal end to Barbut's cannula 10 (Barbut, col. 17, lines 61-62), making it impossible for Barbut's filter 75 to be received into the lumen of Barbut's cannula 10. Contrary to the assertion on page 2 of the Office action, Barbut does not teach that element 317 is an intracardiac device, for example, a prosthetic occluder. Rather, element 317 is an inflation seal attached to a filter mesh 318 that makes up the filtration assembly 315. Barbut, col. 22, lines 49-51. Barbut's filtration assembly has a filter mesh that must permit blood flow rates as high as 3-6 L/min. Barbut, col. 12, lines 6-14. Accordingly, Barbut's filtration assembly is not an intracardiac device, as required by Applicants' claimed invention.

Applicants further submit that Barbut does not teach or suggest a system or method for implanting or retrieving an intracardiac device to a defect at an anatomical site in a patient.

Instead, Barbut teaches transient introduction of an occluding balloon and a porous mesh filter into the vessel of a patient to capture and remove loose embolic material from the patient's blood during surgery without unduly disrupting the patient's blood flow. Following the surgical procedure, Barbut's device is removed. At no time is Barbut's device introduced into an anatomical defect. Barbut, col. 12, lines 6-16 and col. 20, lines 5-25.

Accordingly, for at least the reasons given above, Applicants submit that claims 1, 14 and 27 are patentable over Barbut under 35 U.S.C. § 102(b). Pending claims 4, 5, 11-13, 17, 18 and 24-26 depend from claims 1, 14 or 27 and are therefore patentable over Barbut for at least the same reasons as claims 1, 14 and 27. Applicants respectfully request that the rejection of claims 1, 4, 5, 11-13, 14, 17, 18 and 24-27 be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 103(a)

Dependent claims 2, 3 and 6-10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Barbut as applied to independent claim 1 above. Dependent claims 15, 16 and 19-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Barbut as applied to independent claim 14 above. Dependent claim 28 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Barbut as applied to independent claim 27 above. Claims 2, 3 and 6-10 depend from amended independent claim 1, claims 15, 16 and 19-23 depend from amended independent claim 14 and claim 28 depends from amended independent claim 27. Applicants submit that dependent claims 2, 3 and 6-10, 15, 16, 19-23 and 28 are patentable for at least all of the reasons provided above for the patentability of independent claims 1, 14 and 27. Applicants request that the rejection of claims 2, 3 and 6-10, 15, 16, 19-23 and 28 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Independent claim 29 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Barbut. Claim 29 recites a method for retrieving a collapsible intracardiac device from a patient comprising providing a front-end loader comprising an expanded lumen and a distal portion comprising a tube comprising a proximal end, a distal end, a lumen extending therethrough, and a beveled end. Applicants' claimed beveled end is positioned at the distal end of the tube and the beveled end is chamfered. Applicants' claimed method further comprises receiving the

intracardiac device in the lumen of the tube and retrieving the intracardiac device from the patient.

As discussed above with respect to independent claims 1, 14 and 27, Applicants submit that claim 29 is patentable over Barbut at least because Barbut does not teach or suggest receiving an intracardiac device in the lumen of a tube. Instead, Barbut teaches that both its filter 75 and its balloon occluder 65 are fixed to the outer diameter and around the circumference of Barbut's cannula 10. Barbut, col. 17, lines 1-4; col. 18, lines 32-41; col. 28, lines 30-34 and Figures 1, 2A-2C, 22 and 23. Barbut also teaches that its filter 75 and balloon occluder 65 are removed from the patient in a deflated, fully contracted condition about Barbut's cannula. Barbut, col. 20, lines 12-25. Further, Barbut teaches that its filter mesh 75 is bonded at its distal end to Barbut's cannula 10 (Barbut, col. 17, lines 61-62), making it impossible for the filter 75 to be received in the lumen of Barbut's cannula 10. Applicants request that the rejection of claim 29 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Because Barbut lacks the teaching or suggestion of the recited elements of independent claims 1, 14, 27 and 29, Barbut would not result in the claimed device. Further, Applicants note that, with respect to the rejections under 35 U.S.C. § 103(a), the Office action does not resolve the level of ordinary skill in the pertinent art, does not provide supporting documentary evidence of prior art in the pertinent art or an analogous art teaching each of the elements asserted to be obvious, and does not provides a basis, motivation or suggestion for one of ordinary skill in the art to combine the elements to arrive at the claimed invention as a whole. Therefore, Applicants respectfully submit that the Office action has not established a *prima facie* case of obviousness.

Applicants further submit, based on the foregoing arguments, claims 2, 3 and 6-10, 15, 16, 19-23, 28 and 29 are patentable over Barbut. Applicants request that the rejections of claims 2, 3 and 6-10, 15, 16, 19-23, 28 and 29 be reconsidered and withdrawn.

Information Disclosure Statements

Applicants respectfully request that the Examiner provide a copy of the November 17, 2003 Form PTO-1449 with the C1 reference initialled and a copy of the April 5, 2004 Form PTO-1449 with the B1 and C2 references initialled with the next Office action.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully request allowance of claims 1-3, 5-12, 14-16, 18-25 and 27-30. If the Examiner believes that a telephone conversation with Applicants' attorney would expedite allowance of this application, the Examiner is cordially invited to call the undersigned attorney.

Respectfully submitted,

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